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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,772	08/18/2003	Meir Rosenberg	022719-0046	3663
21125	7590	05/25/2006		
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER HOEKSTRA, JEFFREY GERBEN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/642,772	ROSENBERG, MEIR	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 28-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. In response to the amendment filed on 03/20/2006, amended claims 1 and 18 are acknowledged. The current rejections of the claims 1-27 are withdrawn. The following new and reiterated grounds of rejection are set forth:

### ***Claim Objections***

2. Claims 8-9 and 22-23 objected to because of the following informalities:
3. The term "about" in claims 8 and 22 is a relative term that appears to render the claims indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The length of the slit along the catheter length is unclear.
4. The term "substantially" in claims 9 and 23 is a relative term that appears to render the claims indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The degree of fluid impermeability of the closed catheter slit is unclear.
5. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-11, 13, and 15-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Fonger et al (US 5,291,896).

8. For claims 1 and 18, Fonger et al discloses a catheter drainage system as broadly as *structurally* claimed, comprising: an elongated tube, or catheter, 12 including a distally disposed solid state pressure transducing sensor 14 (column 6 lines 1-41) wherein (a) said sensor is disposed close to, next to, or adjacent the external surface of the distal-most end of the catheter as best seen in Figures 1 and 2 and (b) said sensor *functions* to measure pressure adjacent the external surface of the distal-most end of the catheter (column 5 lines 4-20 and column 6 lines 1-41), further including at least one wire 24 distally coupled to the sensor and proximally mated to an antenna, a metallic apparatus including a wire for sending or receiving electromagnetic waves 26 (column 5 lines 4-20), for electrical powering, communicating and extending along the length of the catheter in fluid isolation from the inner lumen 40 and wherein the at least one wire being proximally separable from the elongated tube through a slit 46 such that the tube length is selectively adjustable (column 2 lines 30-35 and column 4 lines 32-44)).

Furthermore, the slit 46 extends through the outer wall 15 of the tube 12 into the second lumen 42 such that the at least one wire can be partially removed to adjust the tube length.

9. For claims 2 and 11, Fonger et al discloses the at least one wire 24 disposed within a second lumen 42 isolated from the first and wherein the slit 46 extends into the second lumen).

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10. For claim 3, 6-10, and 21-24, Fonger et al discloses a slit 46 extending through the outer wall 15 of the tube 12 into the second lumen 42 such that the tube length is selectively adjustable (column 4 lines 32-44). The slit 46 is configured such that the at least one wire can be partially removed to adjust the tube length and when said wire(s) is/are inserted they are in substantial fluid isolation via the sealing action of the polymer. The slit 46 is configured (column 4 lines 6-10) to extend along a distance less than the length of the catheter and less than about one half the length of the catheter as best seen in Figure 1.

11. For claims 4 and 19, Fonger et al discloses a first lumen diameter greater than the second lumen diameter (column 3 lines 60-66).

12. For claims 5 and 20, Fonger et al discloses multiple secondary lumens 84,86,88,90 formed within an invagination of the outer tube wall 12 as best seen in Figure 7.

13. For claims 13 and 25, Fonger et al discloses the use of a flexible, biocompatible polymer (column 3 lines 41-42).

14. For claims 15-17 and 26-27, Fonger et al discloses a distally disposed pressure sensor (column 6 lines 13-18) adapted to sense physiological conditions adjacent to the elongated tube and disposed within the secondary lumen with an inner diameter of 10 French (column 3 lines 63-66) which is equal to approximately 3.3 mm or 0.131 inches.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fonger et al in view of Quackenbush (US 5,104,398). Fonger discloses the claimed sensor catheter drainage system except for (a) the polymer selected from a group consisting of silicones, silicone-like materials, and polyurethanes and (b) the at least one wire is disposed within a secondary catheter coupled to the first that can be peeled apart to allow the catheter length to be adjusted independent the length of the secondary catheter. Quackenbush discloses a membrane splitting tube 10 comprised of polyurethane (column 3 line 23) with a catheter or wire inserted in an outer peel-away membrane (column 1 lines 33-41). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the trimmable sensing catheter as taught by Fonger et al, with the polyurethane splitting tube of Quackenbush for the purpose of configuring an implantable fluid management device, including a catheter having at least one wire running there through, which is coupled to a sensor disposed at a distal portion of the catheter, for use in advanced medical procedures requiring pressure management whilst draining fluid.

### ***Response to Arguments***

17. Applicant's arguments with respect to claims 1-27 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH

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